

OpenStudyBuilder

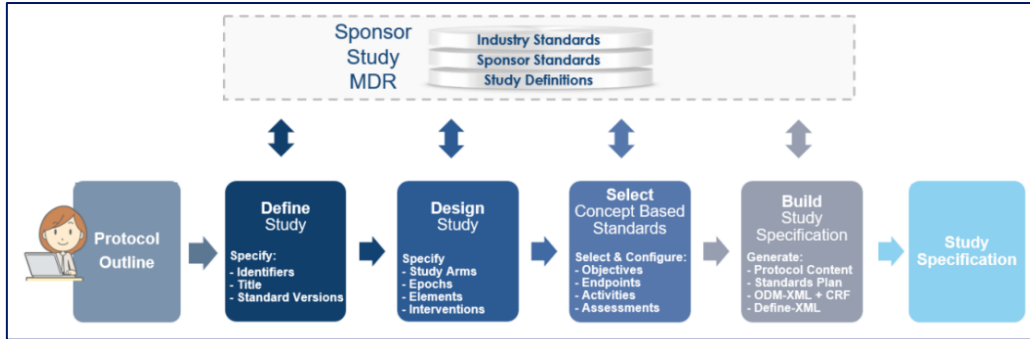
CDISC DEUN UG

OPEN
STUDY
BUILDER

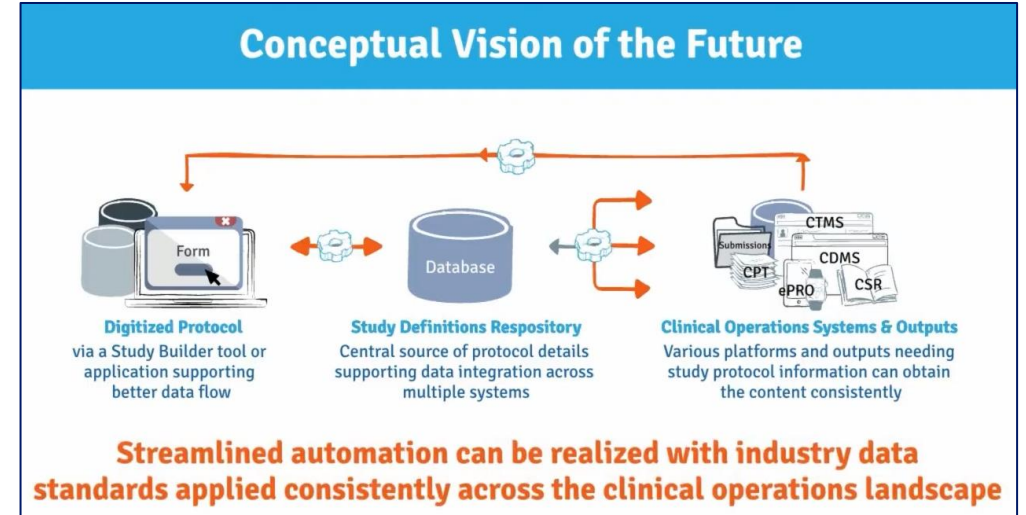


Introduction

CDISC 360°



TransCelerate Digital Data Flow



OpenStudyBuilder
Open-Source by Novo Nordisk

Introduction

The OpenStudyBuilder comprises three elements:

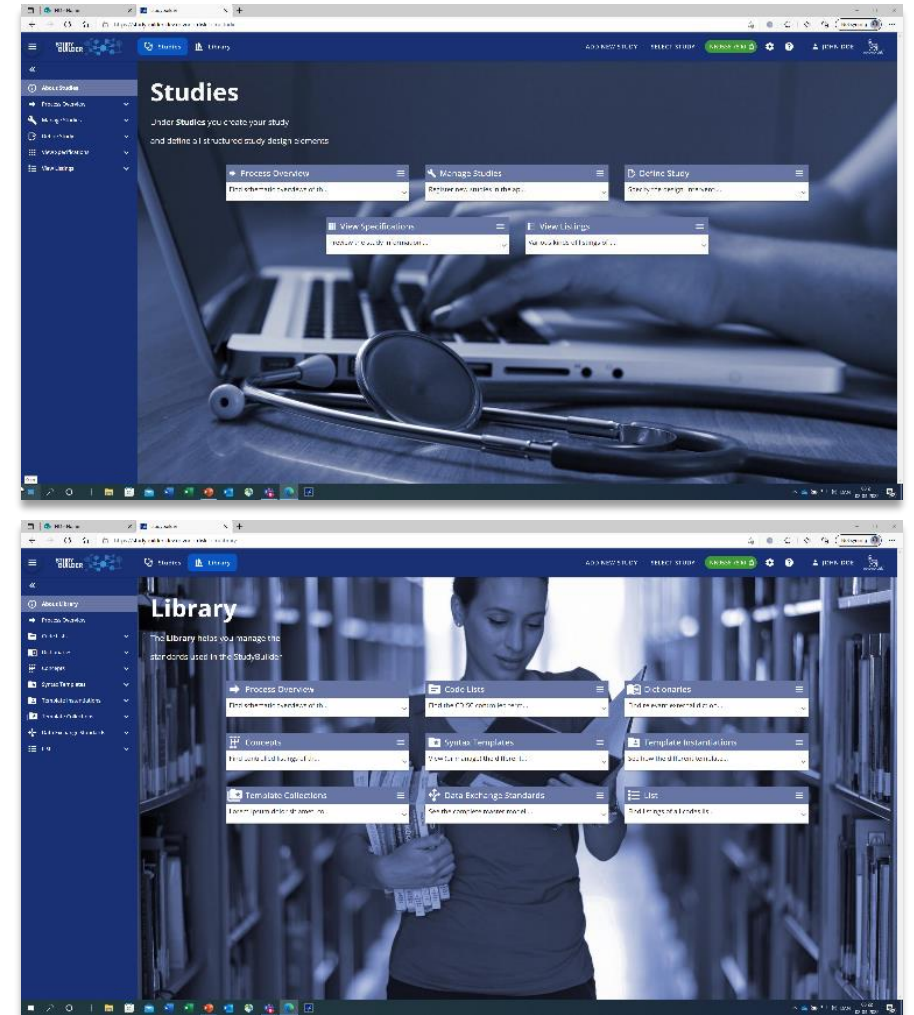
- **Clinical Metadata Repository (clinical MDR) & Study Definition Repository (SDR)**
(graph database, central repository for all study specification data)
- **OpenStudyBuilder application**
(web-based user interface)
- **API layer**
(allowing interoperability with other applications)
(DDF API Adaptor – enabling DDF SDR Compatibility)



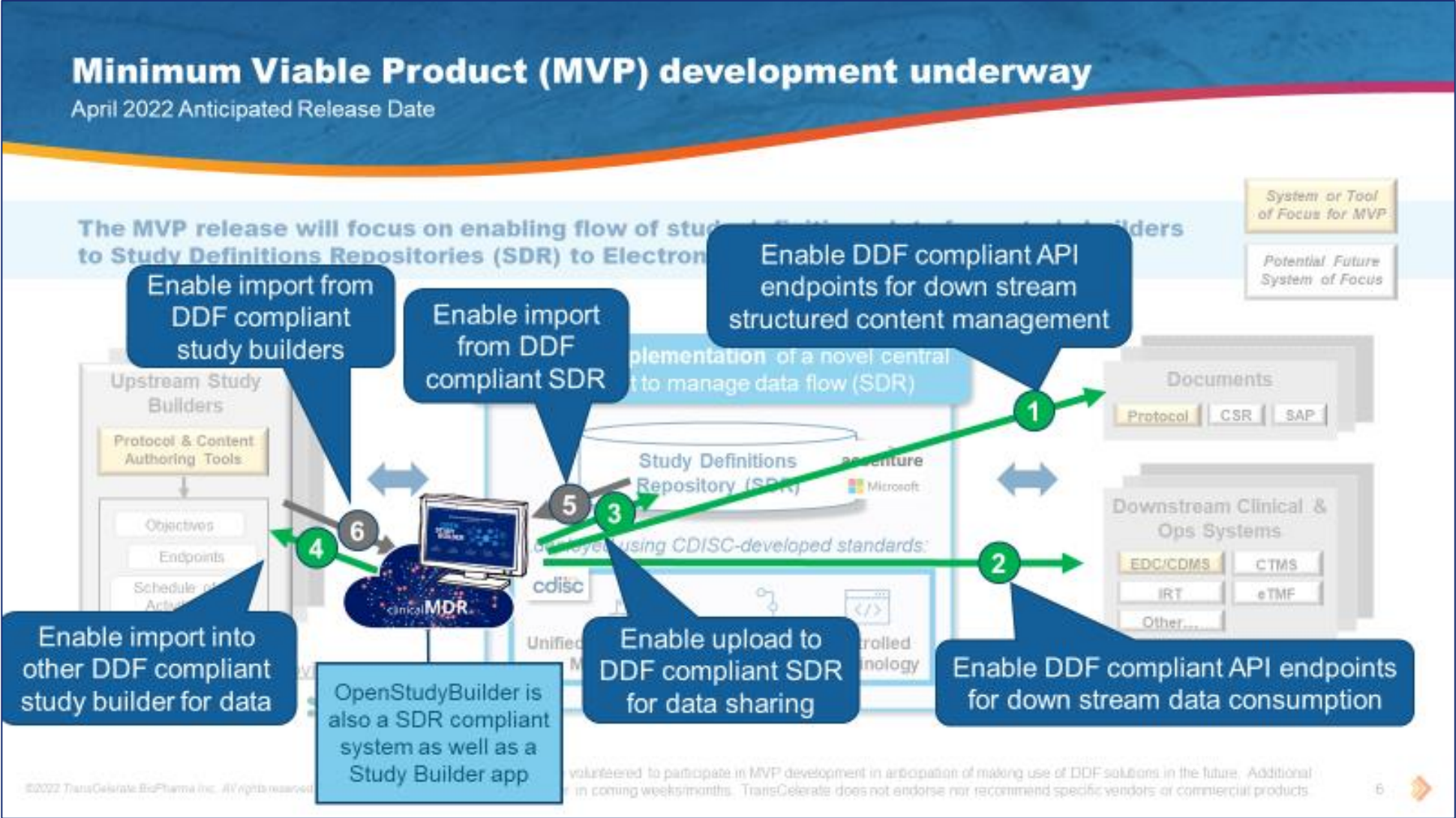
Introduction

The OpenStudyBuilder includes:

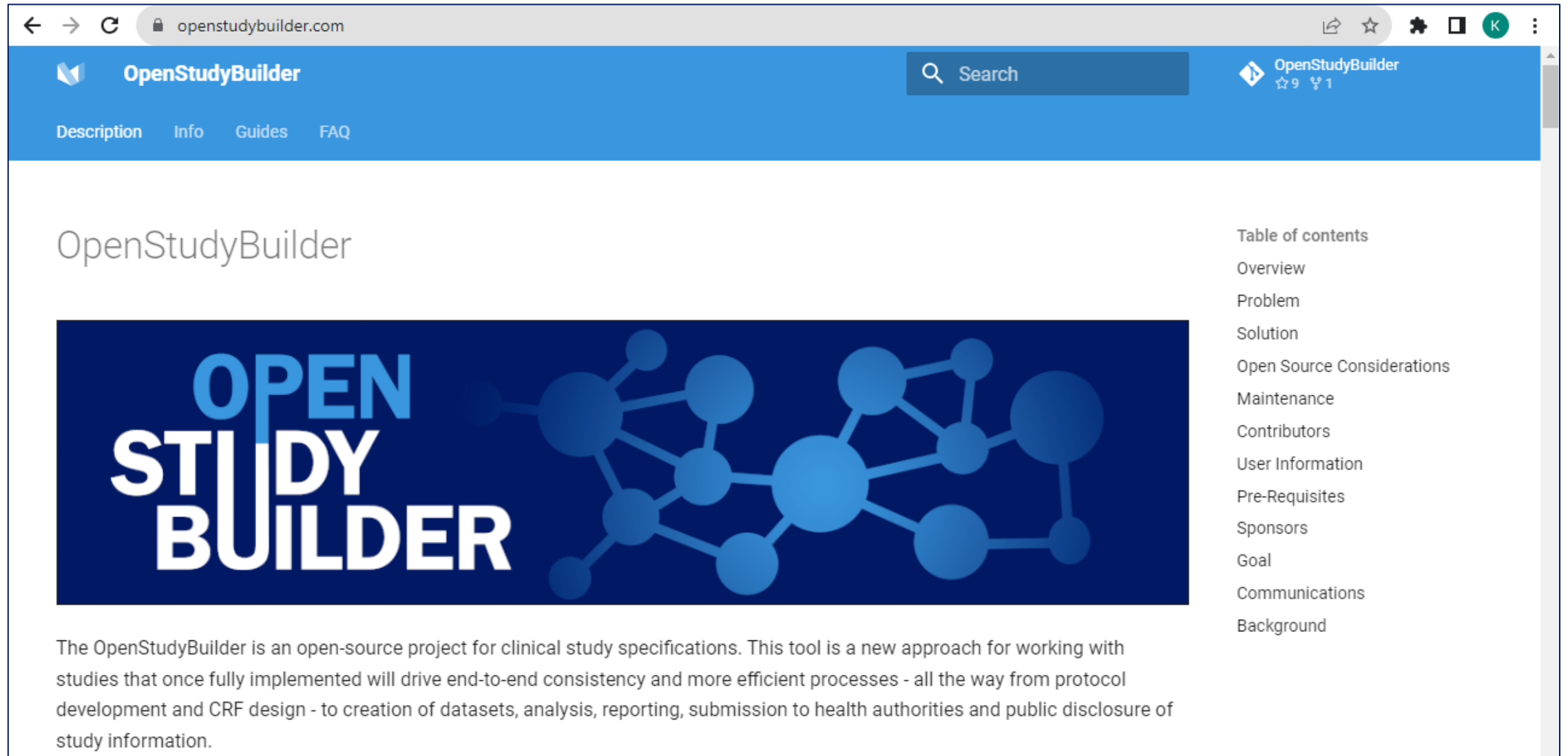
- A **Studies** part for specification of studies (incl. disease area and study type, objectives and endpoints, population and eligibility criteria, study compounds and other interventions, study design, arms and visits, schedule of activities and associated procedure and assessment instructions)
- A **Library** part for maintenance of terminology standards (incl. CDISC controlled terminology, relevant parts of external dictionaries for medical terms, pharmacological classes, units, a detailed compound library, a granulated library of activity terms) as well as syntax templates for cross-study and cross-project harmonisation)
- An underlying **knowledge database** (enabling complex queries and visualisations for aggregation of information and showing how things are connected end-to-end)



OpenStudyBuilder will also be DDF Compatible



Project Homepage



The screenshot shows a web browser window with the URL openstudybuilder.com. The page features a blue header with the OpenStudyBuilder logo, a search bar, and navigation links for Description, Info, Guides, and FAQ. The main content area includes the text "OpenStudyBuilder" and a large blue banner with the text "OPEN STUDY BUILDER" and a network diagram. A table of contents is listed on the right side of the page.

OpenStudyBuilder

**OPEN
STUDY
BUILDER**

The OpenStudyBuilder is an open-source project for clinical study specifications. This tool is a new approach for working with studies that once fully implemented will drive end-to-end consistency and more efficient processes - all the way from protocol development and CRF design - to creation of datasets, analysis, reporting, submission to health authorities and public disclosure of study information.

Table of contents

- Overview
- Problem
- Solution
- Open Source Considerations
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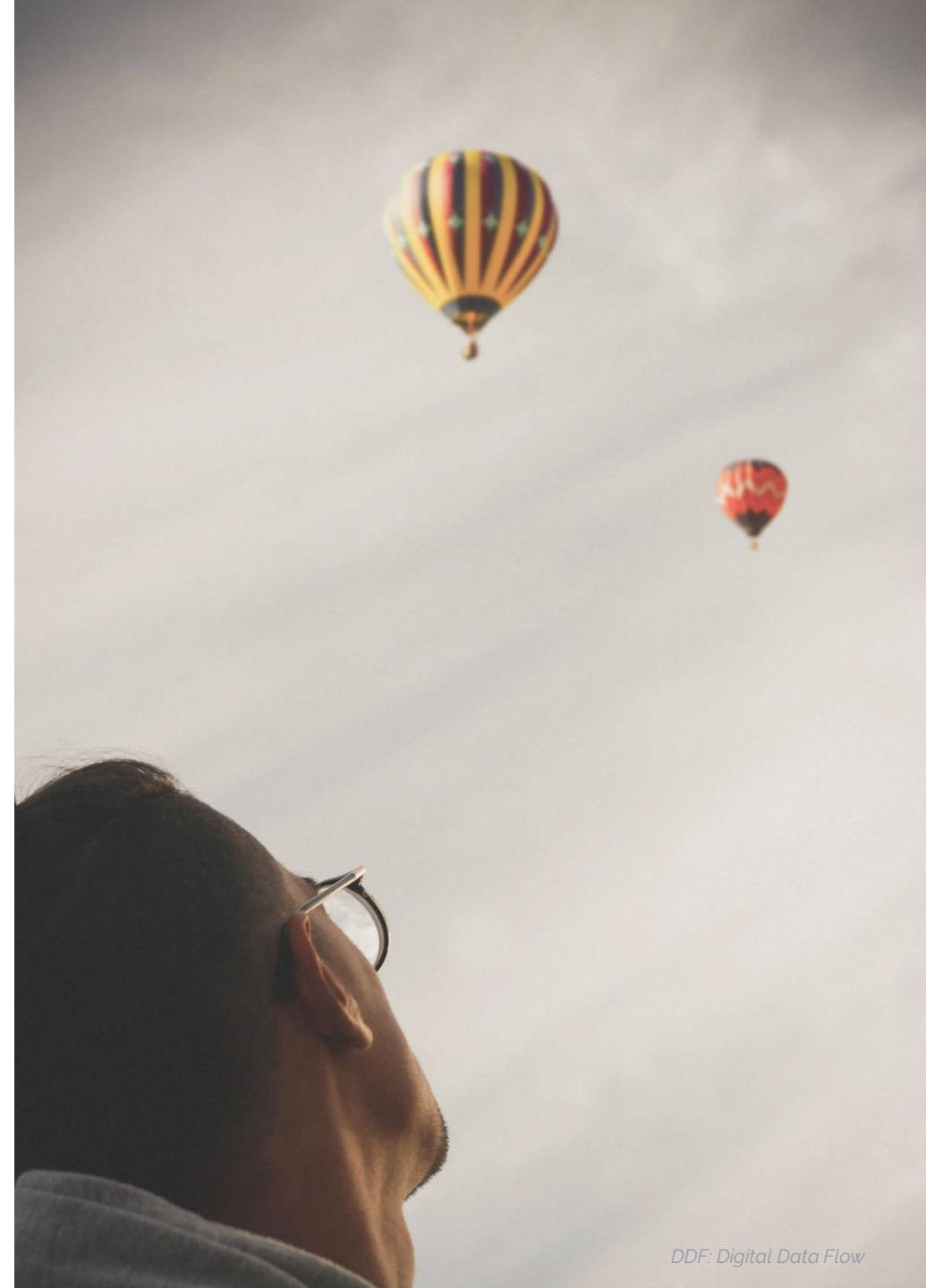
<https://openstudybuilder.com/>

Links

- Project Homepage: <https://openstudybuilder.com/>
- YouTube Demonstration (30'): <https://youtu.be/dL5CY0BwfEs>
- GitLab (Solution, Description): <https://gitlab.com/Novo-Nordisk/nn-public/openstudybuilder>
- Slack:
https://join.slack.com/t/openstudybuilder/shared_invite/zt-19mtauzic-Jvrhtmy7hGstgyilvB1Wsw
- E-Mail: openstudybuilder@gmail.com

Sandbox:

- Mail openstudybuilder@neotechnology.com – Subject “Request Sandbox access”
- Note: when add/modify/delete, you mail might be exposed in the version history



Getting along

- **Support**

- Documentation
- OpenStudyBuilder Q&A sessions
- Slack & Mail
- Commercial support options of vendors

- **Share**

- Documentation, Feedback, Ideas
- Enhancements, connected tools
- Biomedical Concepts discussions & additions
- Remark: no direct contribution in repository

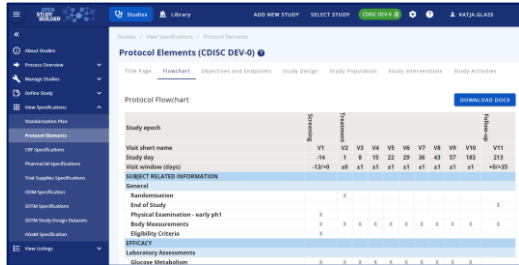


OpenStudyBuilder – What's in?

What do I get?

- /// Documentation
 - Project Homepage
 - Tool documentation
 - GitLab documentation
 - Database design
 - Architecture design
 - Instructions

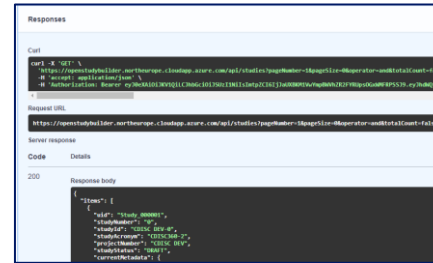
Application



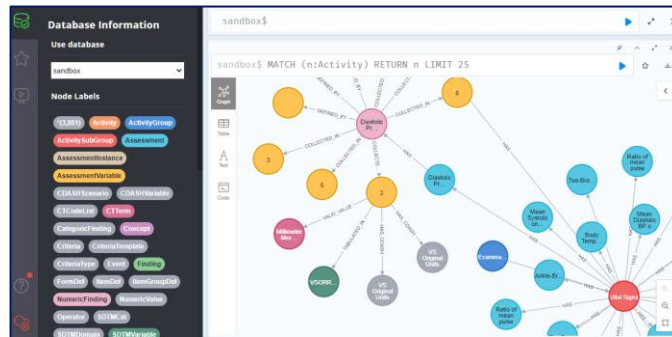
Neo4j database
- Including example data



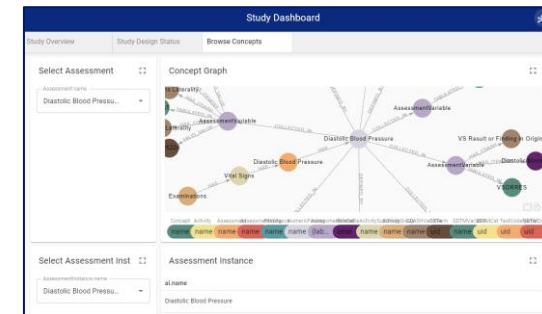
API



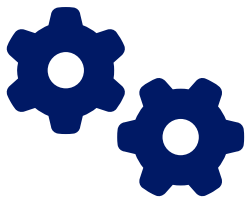
DB Browser



Neo4j dashboard*



Scripts



*available in sandbox, can be installed on other environments



Sandbox

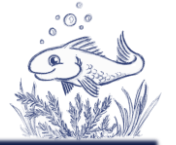
- **OpenStudyBuilder App**
<https://openstudybuilder.northeurope.cloudapp.azure.com/>
- **Documentation**
<https://openstudybuilder.northeurope.cloudapp.azure.com/doc/>
- **NeoDash**
<https://openstudybuilder.northeurope.cloudapp.azure.com/neodash/>
- **(DB Browser)**
<https://openstudybuilder.northeurope.cloudapp.azure.com/browser/>
- **(Bloom)**
<https://openstudybuilder.northeurope.cloudapp.azure.com/bloom/>

Questions!

OPEN
STUDY
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SDR Use Cases



Protocol Automation

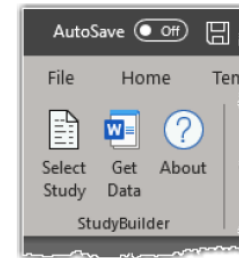
- Word Add-In open-source release planned by Novo Nordisk



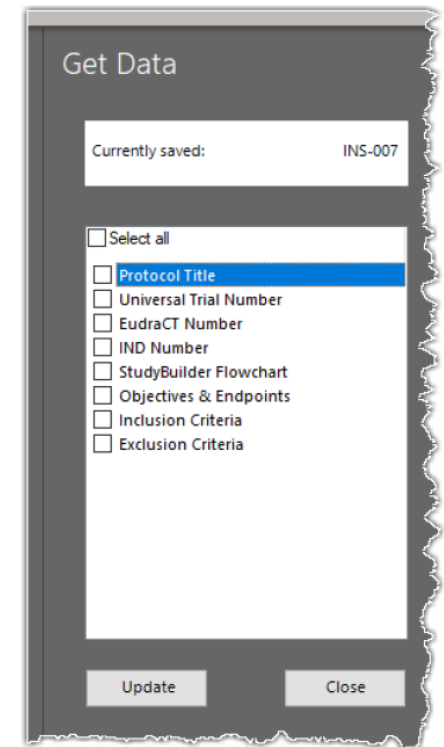
StudyBuilder ribbon (Word add-in)



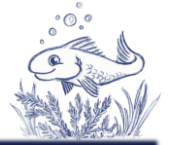
- ✓ One-way connection
- ✓ Code recognizes the document type
- ✓ User-friendly ribbon and 'fly-out' in Word
- ✓ Styles ensure proper formatting in Word



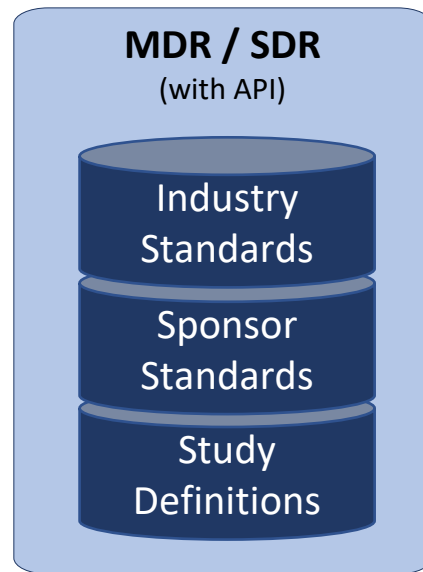
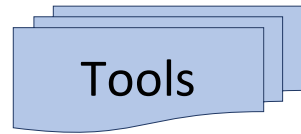
Protocol



SDR Use Cases



Within OpenStudyBuilder Universe



Plugin
Extension
Stand-alone tools

